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CASWELL FILE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

009471

APR 28 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: 2,4-Dichlorophenoxyacetic Acid: Generic Data Submission as Required in the 2,4-D Registration Standard.

FROM: Jess Rowland, M.S, Toxicologist Jess Rowland 4/22/92
Section II, Toxicology Branch II
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TO: W. Waldrop/ J. Coombs
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THRU: K.Clark Swentzel, Section Head K. Clark Swentzel 4/23/92
Sectior II, Toxicology Branch II
Health Effects Division (H7509C)
and
Marcia van Gemert, Ph.D., Chief Marcia van Gemert 4/24/92
Toxicology Branch II
Health Effects Division (H7509C)

PROJECT IDENTIFICATIONS: Submission S414723 Case No. 818706

Caswell No. 315 HED Project No. 2-1863

ACTION REQUESTED: Review MRID No. 422327-01 for Guideline 81-5; Primary Dermal Irritation Study in Rabbits

RESPONSE: As detailed in the attached Data Evaluation Report, the dermal irritation potential of technical grade 2,4-dichlorophenoxyacetic acid [96.7%], was evaluated in male and female New Zealand White rabbits. The test material was shown to be a non-irritant in the rabbit skin.

TOXICITY CATEGORY: IV

CORE CLASSIFICATION: Guideline; satisfies Guideline requirement [81-5] for a primary dermal irritation study.

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PRIMARY REVIEWER: Jess Rowland, M.S, Toxicologist
Section II, Toxicology Branch II

SECONDARY REVIEWER: K. Clark Swentzel, Section Head
Section II, Toxicology Branch II

DATA EVALUATION REPORT

STUDY TYPE: Primary Dermal Irritation **GUIDELINE:** 81-5

Caswell No. 315 **MRID No. 422327-01** **HED PROJECT No. 2-1863**

TEST MATERIAL: 2,4-Dichlorophenoxyacetic acid

REGISTRANT: Industry Task Force II for 2,4-D Research Data

TESTING LABORATORY: The Toxicology Research Laboratory,
Dow Chemical Company, MI

STUDY IDENTIFICATION: K-002372-060

TITLE OF REPORT: 2,4-Dichlorophenoxyacetic Acid: Primary Dermal Irritation Study in New Zealand White Rabbits.

AUTHOR: N.M. Berdasco

REPORT DATE: January 30, 1992

CONCLUSION: The dermal irritation potential of technical grade 2,4-dichlorophenoxyacetic acid [96.7%], was evaluated in male and female New Zealand White rabbits. The test material was shown to be a non-irritant in the rabbit skin.

TOXICITY CATEGORY: IV

CORE CLASSIFICATION: Guideline; satisfies Guideline requirement [81-5] for a primary dermal irritation study.

I. INTRODUCTION

This Data Evaluation Report (DER) summarizes the experimental procedures and results of a primary dermal irritation study with 2,4-D Acid in rabbits.

II. MATERIALS AND METHODS

1. Test Material

Common Name:	2,4-dichlorophenoxyacetic acid
Lot No.	909
Purity:	96.7%
Description:	White powder

2. Test Animals

Species: Rabbits
Strain: New Zealand White
Sex: Males and Females
Weight: 3.3 - 3.8 kg
Identification: Ear tags.

3. Animal Husbandry

Housing: 1/cage.
Food: Purina Certified Rabbit Chow #5322 ad libitum
Water: tap water ad libitum
Environment: "Adequate environmental conditions'

4. Treatment

A dose of 0.5 g of undiluted test material was applied to the intact skin of shaved backs [15 x 15 cm area] of three male and three female rabbits under a 4x4 cm gauze patch that was held in place with non-irritating adhesive tape. The gauze patch was moistened with 0.5 mL of distilled water to ensure sufficient skin contact and covered with a flannel bandage taped to the marginal hair of the rabbits. The wrapping and gauze patch were removed after a four-hour exposure period and the back was wiped with a damp disposable towel to remove any residual test substance. The application sites were examined and graded for erythema, edema, and necrosis within 30 minutes and 24, 48 and 72 hours after patch removal.

5. Quality Assurance

A quality assurance statement was signed and dated on January 30, 1992.

III. RESULTS

None of the animals showed any signs of irritation during the observation period. The primary irritation score was 0. Thus, this material was not considered a primary irritant.

IV. CONCLUSION: The dermal irritation potential of 2,4-dichlorophenoxyacetic acid [96.7%] was evaluated in male and female New Zealand White rabbits. The test material was shown to be a non-irritant in the rabbit skin.

TOXICITY CATEGORY: IV

V. CORE CLASSIFICATION: Guideline; satisfies Guideline requirement [81-5] for a primary dermal irritation study.

Tox Chem No. 315 File Last Updated _____ Current Date 4/20/92

STUDY/LAB/STUDY #/DATE	MATERIAL	EPA MRID NO.	RESULTS: LD50, LC50, PIS, NOEL, LEL	TOX CATEGORY	CORE GRADE/DOC. #
81-5 Primary Dermal Irr. Species: Rabbits E-002572-060 Dow;01/30/92	2,4-D Acid Tech;96.7%	422527-01	0.5 g neat compound; non-irritant; PIS= 0	IV	Guideline MR

NEW INPUT

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